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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,207	02/24/2004	Shanta Modak	070050,2534	8835
21003 7590 03/05/2009 BAKER BOTTS L.L.P. 30 ROCKEFELLER PLAZA 44TH FLOOR NEW YORK, NY 10112-4498				
EXAMINER				
SOROUSH, ALI				
ART UNIT		PAPER NUMBER		
1616				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DL.NYDOCKET@BAKERBOTTS.COM

Office Action Summary

Application No.

10/785,207

Applicant(s)

MODAK ET AL.

Examiner

ALI SOROUSH

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-10, 12, 13, 16, 19, 20, 22, 33 and 34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1-5, 7-10, 12, 13, 16, 19, 20, 22, 33, and 34 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgment of Receipt

Applicant's response filed on 12/18/2008 to the Office Action mailed on 09/22/2008 is acknowledgment.

Status of the Claims

Claims 13 and 16 are currently amended and claims 6, 11, 14, 15, 17, 18, 21, and 23-32 are cancelled. Therefore, claims 1-5, 7-10, 12, 13, 16, 19, 20, 22, 33, and 34 are pending examination for patentability.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 1, 2, 3, 5, 7-10, 12, 13, 16, 19, 20, and 22 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-11, and 17 of copending Application No. 10/622272 **is maintained**.

Response to Applicant's Arguments

Applicant argues that since the overlapping claims have not yet been patented Applicants will agree to submit a terminal disclaimer at such necessary time. Therefore, the instant rejection of claims 1, 2, 3, 5, 7-10, 12, 13, 16, 19, 20, and 22 on the ground of nonstatutory obviousness-type double patenting is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is maintained**.

Claim 16 lacks antecedent basis for reciting "the quaternary ammonium compound" in claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. The rejection of claims 1-3, 5, 7, 9, 19, 20, 22, 33, and 34 under 35 U.S.C. 103(a) as being unpatentable over Modak et al. (US Patent 5965610, Published 10/12/1999) in view of Burnier et al. (US Patent 5736574, Published 04/07/1998) is **maintained**.

Applicant Claims

Applicant claims a composition comprising alcohol, water, hydrogel, an emollient, octoxyglycerin and an antimicrobial.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Modak et al. teaches a topical composition comprising a gel formed between zinc gluconate and solvent selected from the group consisting of water and alcohol and mixtures thereof, and further comprising a thickening agent, a hydrophobic polymer, an emulsifying agent, an emollient, and an antioxidant. The thickening agent is selected from a stearyl alcohol and cationic hydroxyethyl cellulose; the hydrophobic polymer is

selected from dimethicone, petroleum and byproducts thereof; the emulsifying agent is selected from PEG-14M and Incroquet Behenzyl TMS. The zinc gluconate is useful as an anti-irritant effect on the skin. The composition can further include antimicrobials. (See abstract, column 26, Lines 14-67 and column 27, Lines 1-14).

Burnier et al. teach combinatorial antimicrobial immixtures comprising N-n-octanoglycine and an antimicrobially synergistically effective amount of octoxyglycerin which are well suited for formulations in a wide variety of pharmaceutical and cosmetic compositions. (See abstract and Example 1 and 2).

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Modak et al. lacks a composition comprising a synergistic mixture of octoxyglycerin and an antimicrobial. This deficiency is cured by the teachings of Burnier et al.

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add the antimicrobial immixture taught by Burnier et al. to the composition taught by Modak et al., as suggested by Burnier et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Burnier et al. teach that the immixture is useful in cosmetic compositions and Modak et al. teach that the composition can further comprise antimicrobials.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Applicants Arguments

Applicant argues one of ordinary skill in the art would not expect success combining that the antimicrobial composition taught by Burneir et al. with the topical formulation taught by Modak et al. since Modak et al. only exemplifies the topical formulation comprising antimicrobial chlorhexidine and one would not expect success of combining other antimicrobial with the surface binding inhibitors taught. Applicant's arguments have been fully considered but found not to be persuasive. Modak et al. does not limit the composition to chlorhexidine antimicrobials but includes a wide variety of antimicrobials including those taught by Burneir et al. (See Modak et al. column 4, Lines 57-67 and Column 5, Lines 1-40).

Applicant further argues that the combined teachings of Modak et al. and Burnier et al. lack a teaching wherein the formulation has a viscosity of 2000 centipose. Applicant's argument has been fully considered but found not to be persuasive. It is the Examiners position that the combine teachings of Modak et al. and Burneir et al. make

implicit the instantly claimed viscosity. For the foregoing reasons the instant rejection of claims 1-3, 5, 7, 9, 19, 20, 22, 33, and 34 under 35 U.S.C. 103(a) is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number For the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
Patent Examiner
Art Unit: 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616